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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,975	04/21/2004	Dejian Ren	110313.136US2	9673
23483	7590	09/07/2005	EXAMINER	
WILMER CUTLER PICKERING HALE AND DORR LLP 60 STATE STREET BOSTON, MA 02109			SZPERKA, MICHAEL EDWARD	
		ART UNIT	PAPER NUMBER	
		1644		

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

<b>Application No.</b> 10/828,975	<b>Applicant(s)</b>	
	REN ET AL.	
<b>Examiner</b> Michael Szperka	<b>Art Unit</b> 1644	

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 18 February 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1-26, 29-51, 53, 61, 64, 72, 75, 86, 89, 92, 94 and 101 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-26, 29-51, 53, 61, 64, 72, 75, 86, 89, 92, 94, and 101 are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   |   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
|  | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Applicant's preliminary amendment received February 18, 2005 is acknowledged.

Claims 27, 28, 52, 54-60, 62, 63, 65-71, 73, 74, 76-85, 87, 88, 90, 91, 93, 95-100, and 102-111 have been cancelled.

Claims 5, 12, 15, 16, 19-23, 30-32, 35-38, 46, 65, 67, and 69 have been amended.

Claims 1-26, 29-51, 53, 61, 64, 72, 75, 86, 89, 92, 94, and 101 are pending in the instant application.

***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 8, and 12-25, drawn to nucleic acid probes for SEQ ID NO:1, vectors, host cells, and kits comprising said probes, classified in class 536, subclass 24.31 and class 435, subclass 325.

II. Claims 2, 8, and 12-25, drawn to nucleic acid probes for SEQ ID NO:3, vectors, host cells, and kits comprising said probes, classified in class 536, subclass 24.31 and class 435, subclass 325.

- III. Claims 3, 8, and 12-25, drawn to nucleic acid probes for SEQ ID NO:5, vectors, host cells, and kits comprising said probes, classified in class 536, subclass 24.31 and class 435, subclass 325.
- IV. Claims 4-25, drawn to nucleic acids encoding functional CatSper2 polypeptides or domains thereof, vectors, host cells, and kits comprising said nucleic acids, classified in class 536, subclass 23.1 and class 435, subclass 325.
- V. Claim 26, drawn to transgenic animals containing a Catsper2 sequence, classified in class 800, subclass 8.
- VI. Claims 29-32, drawn to CatSper2 polypeptides, classified in class 530, subclass 300.
- VII. Claims 33-40, drawn to antibodies and kits containing antibodies specific for CatSper2 polypeptides, classified in class 530, subclass 387.9.
- VIII. Claims 42 and 46, drawn to methods of identifying modulators that increase CatSper2 activity using mRNA, classified in class 536, subclass 24.1.

- IX. Claims 42 and 46, drawn to methods of identifying modulators that decrease CatSper2 activity using mRNA, classified in class 536, subclass 24.5.
- X. Claims 43 and 46, drawn to methods of identifying modulators that increase CatSper2 activity using polypeptides, classified in class 435, subclass 7.2.
- XI. Claims 43 and 46, drawn to methods of identifying modulators that decrease CatSper2 activity using polypeptides, classified in class 435, subclass 7.92.
- XII. Claims 44-46, drawn to methods of identifying modulators that increase CatSper2 activity by measuring ions or currents, classified in class 435, subclass 4.
- XIII. Claims 44-46, drawn to methods of identifying modulators that decrease CatSper2 activity by measuring ions or currents, classified in class 435, subclass 6.

- XIV. Claims 46-47, drawn to methods of identifying modulators that increase CatSper2 activity by measuring sperm motility, classified in class 435, subclass 2.
- XV. Claims 46-47, drawn to methods of identifying modulators that decrease CatSper2 activity by measuring sperm motility, classified in class 435, subclass 806.
- XVI. Claims 48-49, drawn to methods of screening for agents that bind CatSper2, classified in class 435, subclass 7.1.
- XVII. Claims 50-51, drawn to method of administering a compound to males to reduce fertility, classified in class 424, subclass 811.
- XVIII. Claim 53, drawn to a method of administering a compound to females to reduce fertility, classified in class 424, subclass 184.1.
- XIX. Claim 72, drawn to a contraceptive preparation that decreases CatSper2 activity, classified in class 424, subclass 278.1.
- XX. Claims 75 and 86, drawn to methods of identifying mutations in CatSper2 sequences, classified in class 536, subclass 24.31.

XXI. Claim 89, drawn to a method of contacting sperm to zona-removed ova, classified in class 435, subclass 449.

XXII. Claim 92, drawn to a method of transfecting sperm so that they express CatSper2, classified in class 435, subclass 440.

XXIII. Claim 94, drawn to a method of detecting antibody-mediated infertility, classified in class 435, subclass 7.21.

XXIV. Claim 101, drawn to a method of conducting a business, classified in class 705, subclass 500.

3. Claims 61 and 64 are withdrawn from consideration as being drawn to a non-statutory subject matter. Upon amendment, these claims may be grouped with Groups I-XXVII or they may be placed in a separate group and be subject to additional restriction.

The inventions are distinct, each from the other because of the following reasons:

4. Inventions ((I-III) and (VIII, IX, and XX)), (IV and (VIII, IX, XX, and XXII)), (V and (X, XI, XVI, and XXIII)), (VII and XXIII), and (XIX and (XVII and XVIII)) are related as product and process of use. The inventions can be shown to be distinct if either or both

Art Unit: 1644

of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Group VII can be used in the diagnostic method of Group XXIII or in methods of purifying the polypeptide of SEQ ID NO:2. Similarly, the nucleic acid sequences of Group IV can be used in screening assay methods for modulators (Groups VIII and IX), methods of genotyping (Group XX) and methods of transfecting spermatozoa (Group XXII). As such they are patentably distinct.

5. Inventions I-VII and XIX are different products. As such they differ in their primary structure, this difference in structure imbuing the products with unique functional properties. Disclosure of the structure of any one of the inventions of Groups I-VI and XIX does not necessarily anticipate any of the other inventions. For example, a CatSper2 protein may have been disclosed and characterized using biochemical techniques without any knowledge of the nucleic acid sequence (or potentially even of the polypeptide sequence) of the protein. Also, nucleic acid probes corresponding to CatSper2 sequences do not need encode any functional polypeptide, and often nucleic acid sequences that serve as probes are deposited in databases, such as the EST database, before the full length nucleic sequence or the function of said sequence have been elucidated. All of these diverse structures give rise to unique functional properties that are not interchangeable and are useful in performing distinct processes. For example, a transgenic mouse cannot be administered to an individual to achieve

Art Unit: 1644

contraception, but administration of an anti-CatSper2 antibody may achieve this goal.

Note that while other compounds may decrease CatSper2 functional activity, only the compositions of Group XIX are recited as having the property of being a contraceptive.

As such, all of the products are patentably distinct.

6. Inventions VIII-XVIII and XX-XXIV are different methods. As such they recite different process steps such as administering and detecting, require unique ingredients such as polypeptides, antibodies, nucleic acids, agonists, and antagonists, and achieve divergent goals such as achieving contraception, identifying CatSper2 activity modulators that increase activity (agonists) or decrease activity (antagonists), and running a drug discovery business. Art that anticipates or renders obvious one group would not necessarily anticipate nor render obvious the invention of any other group. Therefore they are patentably distinct.

7. Inventions ((I-III) and (X-XVIII and XXI-XXIV)), (IV and (X-XVIII, XXI, XXIII, and XXIV)), (V and (VIII-XVIII and XX-XXIV)), (VI and (VIII, IX, XII-XV, XVII, XVIII, XX-XXII, and XXIV)), and (XIX and (VIII-XVI and XX-XXIV)) are not related as product and process of use. These inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. In the instant case the different inventions are not taught as being useable together. For example, the transgenic animals of Group V are not useful in performing methods that recite the use of antibodies (Group XXIII) or the administration of contraceptives (Groups XVII and XVIII). As such they are patentably distinct.

8. Claim 41 links inventions VIII-XV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 41. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claim is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

9. Because these inventions are distinct for the reasons given above, because the literature searches required for Groups I-XXIV are not coextensive in that art that anticipates or renders obvious the invention of any one group would not necessarily anticipate or render obvious the inventions of the other groups, and because Groups I-XXIV have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

10. This application contains claims directed to the following patentably distinct species of the claimed invention of Groups IV-VII. The distinct species are the sequence of the CatSper2 sequence used in the recited inventions. Applicant is required to elect a CatSper2 sequence from the following:

- A) SEQ ID NO:1 (nucleic)/SEQ ID NO:2 (polypeptide),
- B) SEQ ID NO:3 (nucleic)/SEQ ID NO:4 (polypeptide), or
- C) SEQ ID NO:5 (nucleic)/SEQ ID NO:6 (polypeptide).

These species are distinct because they differ in their primary structure.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims of Groups IV-VII are generic.

11. This application also contains claims directed to the following patentably distinct species of the claimed invention of Groups IV, VI and VII. In addition to the election of a full length CatSper2 sequence as was indicated in paragraph 10 of this office action, applicant is also required to elect a specific CatSper2 epitope sequence. A single epitope (for example, residues 104-126 of SEQ ID NO:2) is to be chosen from the following:

residues 104-126, 146-166, 176-195, 206-228, 241-262 or 316-340 of SEQ ID NO:2 if SEQ ID NO:2 is elected as per paragraph 10,  
residues 104-126, 146-166, 176-195, 206-228, 241-262 or 316-340 of SEQ ID NO:4 if SEQ ID NO:4 is elected as per paragraph 10, or

residues 102-124, 144-164, 174-193, 204-227, 239-260, or 314-338 of SEQ ID NO:6 if SEQ ID NO:6 is elected as per paragraph 10.

These species are distinct because they differ in their primary structure.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims of Groups IV, VI, and VII are generic.

12. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

Art Unit: 1644

the prior art, the evidence or admission may be used in a rejection under 35

U.S.C. 103(a) of the other invention.

13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.**

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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